Exhibit 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225, Silver Spring, MD 20993-0002 Phone: (301) 796-3334, Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	12/07/2016-12/16/2016*
	FEI NUMBER 3008307735

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Pabbati Reddy Bhaskar Reddy, Vice President Operations

FIRM NAME	STREET ADDRESS
Hetero Labs Limited	TSIIC Pharma SEZ
CITY, STATE, ZIP CODE, COUNTRY Polepally Village, Jadcherla Mandal, Mahaboob Nagar District, Telangana State, 509301, India	TYPE ESTABLISHMENT INSPECTED Oral Solid Dose Drug Product Manufacturer

This document lists observations made by the FDA representatives during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representatives during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
The responsibilities and procedures applicable to the quality control unit are not fully followed.

(1) Specifically, your QA technicians and other individuals were recorded destroying and altering records pertaining to commercial batch manufacturing immediately prior to this regulatory inspection. The loss of data and documents are evidenced by the following:

Through a review of your firms Closed Circuit TV we identified the following:

(a) A document shredder was introduced into your firm's "DOCUMENTS STORAGE AREA" on December 03, 2016 at 15:44, approximately 4 days prior to the current US FDA inspection.

(b) After introduction of the document shredder we observed extensive shredding of what appears to be controlled documents and extensive signing of documents by QA. These documents were of a color consistent with batch packaging records and batch manufacturing records, among other documents. Your firm failed to maintain documentation of what had been shredded.

(c) On December 06, 2016, at (b) (4) we observed that a contract employee with QA removed documents from the shredder and placed them in his pocket.

(d) On December 07, 2016, at approximately 1:13 (in the middle of the night) individuals were shredding documents. Your firm stated this event represented cleaning staff shredding documents.

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(e) Other anomalous events were observed associated with this shredder. Your firm failed to clarify the correlation of introducing the shredder to the "DOCUMENTS STORAGE AREA" prior to the current US FDA inspection.

Your firm's Quality Manager stated that your firm has failed to maintain a log of what documents had been shredded and therefore fulfill their position. Under SOP QA001-11 titled "PREPARATION, REVIEW, APPROVAL, CONTROL AND REVISION OF STANDARD OPERATING PROCEDURE, FORMATS AND DOCUMENT CONTROL", Quality Assurance is responsible for "The storage arrangements must make reasonable provision to prevent loss of or damage to the documents."

(2) On December 12, 2016, we observed the scrap area behind the production area of Buildings (b)(4) and (b)(4) to contain controlled documents that had been discarded:

(a) A balance printout with drug product "(b)(4) " dated "14-Dec-2016". *After discussing this finding with your firm, you failed to explain why the balance printout was post-dated by two days, and therefore indicating an alteration to dates on balances.* Your firm's VP of Operations explained that not all balances are password protected.

(b) A "GMP REPORT" indicating a test result of "PASS" with a start date "11/12/16". Your firm's Vice President of Corporate Quality Assurance initially purported that these test results represented a "credit card print from the market."

(c) A printout indicating an "Abort" event of testing.

(d) A plethora of documents with written numbers and signatures.

(3) On December 07, 2016, we observed controlled documents in shred bins, shredders and trash bins as follows:

(a) In the trash bin outside Building (b)(4) we observed the trash liner contained various controlled documents, including: original test results from November 26, 2016 at 12:52 and cleanroom certification reports from (b)(4) 2005. We observed the Hetero seal and official signatures as a part of this discarded record.

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(b) Inside a metal bin intended for shredding in the QA department Building (b) we observed discarded documents including: a signed and reviewed document dated December 07, 2016, in which it appears that the attachments to the document had been physically removed.

(c) We observed a shredder in the QA portion of Building (b) inside a room termed "DOCUMENTS STORAGE AREA." We observed shreds of documents with the appearance of raw data (written numbers), cleaning logs, and other official documentation. Additionally many of the shreds of paper contained the Hetero seal, and what appeared to be original signatures from both QA and QC.

(d) After observing the shredder in Building (b) as discussed in sub-point c, we proceeded to the QA "DOCUMENTATION CELL" in Building (b) (4) room F2062. We observed the door to the shredder was opened without a box for holding shredded documents; however, we noted shreds of paper inside the shredder. We observed several of these shreds of paper to contain what appears to be a QA stamp and green signatures. Your firm stated there is no documentation to indicate what the contents of the shredder are.

Note: Per SOP QA001-11 entitled "PREPARATION, REVIEW, APPROVAL, CONTROL AND REVISION OF STANDARD OPERATING PROCEDURE, FORMATS AND DOCUMENT CONTROL" QA signs documents in green.

Finally, we observed bins intended for shredding in the QC portion of your firm. Your firm's QC Manager for (b) (4) stated that QC documents are shredded in QA without a corresponding log or documentation.

OBSERVATION 2
Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch

Documentation pertaining to exhibit batches submitted to the Agency are incomplete and inaccurate.

I. Data derived from your firm's programmable logic controller (PLC) for compression machines is inconsistent with batch records and validation reports in support of applications to the Agency:

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(a) Batch record for (b) (4) lot (b) (4) states that compression machine PDE-2010 was (b) (4) run between 10:40 and (b) (4) on 06/13/2015. However, the PLC shows (b) (4) records for this same batch used to support a submission to the Agency termed "(b) (4) " ((b) (4) (b) (4) . Per the PLC record, run "(b) (4) " was initiated 15:01:03 on 06/12/2016, a full day prior to what is indicated on the BR. Your firm failed to provide documentation explaining the (b) (4) separate runs under the same batch number. The process validation report PVR2008-01 is silent with regards to (b) (4) runs under the same batch number.

Furthermore, during the manufacture of this batch, a "Position failure" occurred that was not recorded or investigated.

(b) Batch record for (b) (4) ((b) (4)) lot (b) (4) states that compression machine PDE-2010 with (b) (4) run between 9:40 and (b) (4) on 02/15/2016. However, the PLC shows (b) (4) records for this same batch used to support a submission to the Agency termed "(b) (4) " ((b) (4) (b) (4)). The process validation report PVR2030-00 is silent with regards to (b) (4) under the same batch number. The PLC record shows batch "(b) (4) " was initiated 09:18:54, a compression start time prior to what is indicated on the BR. Your firm failed to provide documentation explaining the (b) (4) separate runs under the same batch number.

Furthermore, during compression, 6 alarms were encountered and not recorded or investigated, including: "Powder low level (b) (4) ", "Production out of range side (b) (4) " and "Production out of range side (b) (4) ".

(c) Batch record for (b) (4) ((b) (4) mg) lot (b) (4) states that compression machine PDE-2010 with a (b) (4) run between (b) (4) and (b) (4) on 05/13/2016. However, the PLC shows (b) (4) records for this same batch used to support a submission to the Agency termed "(b) (4) " ((b) (4) (b) (4)). The process validation report PVR2029-00 is silent with regards to (b) (4) under the same batch number. Per the PLC record, run "(b) (4) " was initiated (b) (4) , a compression start time prior to what is indicated on the BR. Your firm failed to provide documentation explaining the (b) (4) separate runs under the same batch number.

Furthermore, during compression, an alarm was encountered and not recorded or investigated, including: "Production out of range side (b) (4) ".

Note: The clock for PLC-2010 and clock in the room housing PLC-2010 were precise.

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For sub-points a – c, we were unable to reconcile the times listed in the BRs versus that indicated in the PLC, such that it is not apparent that BRs are completed contemporaneously.

Of your firm's (b)(4) pending (b)(4), (b)(4) of (b)(4) fail to have reviewable alarm histories. Furthermore, (b)(4) of (b)(4) batches requiring compression for (b)(4) pending (b)(4) are conducted on equipment PDE-072, the sole compression machine that fails to retain electronic raw data.

We reviewed logbook QAR0012/16 (PD) [January 1, 2016 through August 20, 2016] for unplanned deviations pertaining to production and noted that approximately 23% relate to deviations in compression, with the majority reflecting low compression yields and tablet defects.

II. Alarms occurring during the manufacture of submission/ validation batches are not documented, recorded or investigated.

(a) During the manufacture of (b)(4) (b)(4) mg Tablets batch (b)(4), 13 alarms are indicated in the PLC. Some of these alarms pertain to "(b)(4) compression (b)(4) out of range" and overall (b)(4) startup events are required. However, the BR fails to capture any of these events and only notes a single start and end time for compression.

The electronic records for the various PLCs note various alarms and human interventions across compression machines during the manufacture of various drug products. Your firm's management stated that it is not the practice of your firm to record these events. Therefore, manufacturing conditions are not captured and reviewable should a product failure be encountered.

OBSERVATION 3
Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

(a) Your firm received a complaint (MCU16-010 product (b)(4) tablets (b) mg lot (b)(4)) for "One tablet in bottle was twice the thickness of all others and it has same markings and color as the other tablets." Your firm then conducted an investigation identifying "the possibility to generate the higher thickness and higher weight tablets is (b)(4) at the (b)(4) stage." The sample subject to the complaint was received form the consumer and your confirmed this weight disparity by measuring a

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weight of (b) (4) mg versus a maximum specification of (b) (4) mg (approximately 170% of specification).

Various parameters had been altered between (b) (4) of batch subject to the complaint and the previous batch of the same product, such as (b) (4) was (b) (4) from (b) (4) to (b) (4) among other adjustments.

Your firm's investigation then concludes "If the patient consume the higher thickness/weight (double the thickness) by inadvertently no impact on the patient health and safety." As a part of preventative and corrective actions, your firm failed to remove the defective product from the market or otherwise ensure patients would not receive thick tablets.

(b) (4) tablets (b) mg lot (b) (4) was provided to the US market.

(b) Your firm received a complaint (MC016-002 product (b) (4) (b) (4) g lot (b) (4) and (b) (4) (b) (4) mg lot (b) (4)) for "dissolution testing at (b) (4) results not meeting to specification limits." Your firm then conducted an investigation identifying all retain sample results were within specification. The sample subject to the complaint was received from the customer and your firm confirmed the dissolution disparity during testing of the complaint sample and a second retain sample. The investigation conclusion states "It is concluded that this batch is showing inconsistence results. This could be a batch specific issue."

After confirmation of the OOS, your firm failed to remove the product from the market.

For points a and b: Per your firm's "QUALITY SYSTEM MANUAL" document QM001-04, "Any batch found to be non-compliance to the specifications related to safety, identity, efficacy, purity and quality shall be recalled from the market. Moreover, according to SOP CQA012-01 titled "PRODUCT RECALL" indicates that a recall is to be initiated in the event of "Non-compliance with specifications (e.g. assay, stability, fill/ weight or dissolution)."

OBSERVATION 4
The written record or copy of the record of an investigation of a complaint conducted in relation to any unexplained discrepancy is not maintained at the establishment where the investigation occurred.

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Consumer complaints are not documented, recorded or investigated.

(I) The following product quality complaints were not investigated, documented or otherwise handled:

Date Received	Product	Batch No.	Complaint Description
12-12-15	(b) (4)	(b) (4)	Lack of drug effect
11-29-15			Lack of drug effect
2-2-16		unknown	Product did not work
5-21-16		unknown	Medication is not working
9-11-16		unknown	Product shape issue
5-11-15		unknown	Lack of drug effect
10-31-16		unknown	Tablet in stool (Note: not an (b) (4))

Note: in some cases your firm indicated further follow-up was needed to ascertain the batch numbers of drug product subject to the complaint. Your firm has failed to define the required attempts to contact the patient in cases of product quality issues (SOP PV001-01 only speaks to adverse events).

On 12/13/2016, your firm's Quality Manager and Assistant Manager of QA confirmed that your firm had not investigated and was not aware of the aforementioned complaints.

The complaints were handled by Clinical Development and Medical Affairs (CDMA), a site not registered with the Agency, who neglected the associated product quality aspects of these complaints.

Your firm failed to investigate additional complaints.

(b) Complaints are received by (b) (4) . (b) (4) then provides the respective complaints to either/both the pharmacovigilance team (CDMA) and Hetero Unit-V. However, there was a discrepancy between the number of complaints (strictly product quality) received by Hetero Unit-

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V when we inquired with Hetero Unit-V, (b) (4) and CDMA. A discrepancy in complaint numbers presented throughout the inspection are indicated as follows:

Source	Number of Complaints Indicated
Hetero Unit-V	34
(b) (4)	17
Hetero CDMA	26

Your firm could not reconcile the disparity of complaints received between your site, CDMA and (b) (4) (b) (4) (marketing for the US market).

OBSERVATION 5
Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

On December 9, 2016, all (b) (4) recently cleaned (b) (4) ((b) (4)) were in a condition unsuitable for the manufacture of drug products:

All (b) (4) s referenced below are not dedicated to a specific drug product.

(a) (b) (4) PDE-369: This (b) (4) equipment was in the "CLEANED" state. We observed white residue on the drug product contact surface of the (b) (4) lining. Furthermore, white reside was observed on the (b) (4) surface above the (b) (4) Additionally, the interior of the transfer line used to move drug product from the (b) (4) to (b) (4) was soiled with (b) (4) residue and a mold like appearance.

The (b) (4) used for control of (b) (4) to the (b) (4) displayed (b) (4) residue / accumulation (the side of the (b) (4) facing the interior of the (b) (4)). Moreover, the line between the (b) (4) and (b) (4) that provides an (b) (4) displayed a reddish-brown discoloration consistent with rust.

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This equipment is used to manufacture the (b) (4) for (b) (4) capsules, the (b) (4) for (b) (4) (b) (4) tablets, the (b) (4) for (b) (4) tablets, and the (b) (4) for (b) (4) tablets for the US market.

(b) (4) PDE-1231: This (b) (4) equipment was recently cleaned. We observed white residue on above the (b) (4) to the (b) (4) (the drug product contact surface). Additionally, the gasket above the (b) (4) (b) (4) displayed an accumulation of a white substance facing the interior of the equipment. Finally, the (b) (4) surface directly above (b) (4) (and thus drug product) exhibited a (b) (4) residue.

The (b) (4) used for control of (b) (4) to the (b) (4) displayed (b) (4) accumulations intercalated in the (b) (4) (the side of the (b) (4) facing the interior of the (b) (4)). Moreover, the line between the (b) (4) and (b) (4) that provides an (b) (4) displayed a reddish-brown discoloration consistent with rust. The (b) (4) to this (b) (4) was deteriorated and discolored.

This equipment is used to manufacture the (b) (4) of (b) (4) tablets for the US market.

For points a – b we reviewed SOP ENO29-04 titled 'PROCEDURE FOR TESTING OF (b) (4) (b) (4) INSTALLED (b) (4) TEST, (b) (4) TEST" is silent with regards to replacement of the aforementioned (b) (4) .

(c) (b) (4) PDE-2095: This (b) (4) equipment was in the "CLEANED" state. We observed a white residue build-up with black specs around the torn gasket of the interior site (b) (4) of the (b) (4) . Your firm's Vice President CQA and Vice President of Operations stated the white residue was an accumulation from cleaning and the black specs were from welding. Furthermore, a (b) (4) residue was observed in the interior (product contact) of the outlet line to this (b) (4) . This (b) (4) is used to manufacture the (b) (4) for (b) (4) Tablets for the US market.

The (b) (4) used for control of (b) (4) directly into the (b) (4) ((b) (4) used) was (b) (4) and in a (b) (4) like state. This (b) (4) is used to manufacture the (b) (4) for (b) (4) Tablets.

(d) (b) (4) PDE-2005: This (b) (4) equipment was in the "CLEANED" state. (b) (4) coloring and (b) (4) coloring were both observed on the product contact surface of the (b) (4) for the (b) (4) . The operator did not know what caused the discolorations and your firm's Vice President of Operations stated it was due to a metal reaction. In addition, (b) (4) particles were observed in the

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interior siding of the (b) (4). This (b) (4) is used to manufacture the (b) (4) for (b) (4) and (b) (4) tablets for the US market.

(e) (b) (4) ((b) (4)) PDE-056: The (b) (4) surface of the equipment was heavily scratched. Document "BREAKDOWN WORK REQUEST NOTE" from February 2016 states "(b) (4) touch on the (b) (4) base." Despite your firm's knowledge of the (b) (4) contacting the base of this (b) (4) equipment, no assessment into potential metal shavings or associated product impact was conducted. This equipment is used to manufacture the (b) (4) for (b) (4) (b) (4) Tablets for the US market.

OBSERVATION 6
Deviations from production time limits are not documented.

Excursions in hold time are not investigated, trended or otherwise evaluated for product impact. The following table contains examples of drug products and number of hold time excursions:

Drug Product	Number of Hold Time Excursions
(b) (4) Tablets (b) (4) g	6
(b) (4) g	7
(b) (4) Tablets (b) (4) mg	6
(b) (4) Tablets (b) (4) mg	3
(b) (4) mg	4

Your firm's Annual Product Quality Review was silent in regards to manufacturing hold time excursions.

Your firm's Quality Manager qualified this practice by referencing SOP QA058-07, which states "In case during commercial manufacturing if the product exceeds the established hold time period at any

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	FEI NUMBER 3008307735

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Pabbati Reddy Bhaskar Reddy, Vice President Operations

FIRM NAME	STREET ADDRESS
Hetero Labs Limited	TSIIC Pharma SEZ
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Polepally Village, Jadcherla Mandal, Mahaboob Nagar District, Telangana State, 509301, India	Oral Solid Dose Drug Product Manufacturer

stage, sample shall be collected as per SOP No QA023 (for Block (b) (4)) or as per SOP QA086 (for block (b) (4) by IPQA person and shall be submitted to QC for re-testing as per SOP No QC018."

OBSERVATION 7

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

(1) For Method Verification Report MVR/16/2023 for determination of Particle Size for (b) (4) :

On December 09, 2016, we observed 2 files for the Mastersizer 3000 used to commence method verification of particle size for (b) (4) tablets. Specifically, we observed files are termed "(b) (4) -MSC1600188 (Precision)" and "(b) (4) -MSC1600188 (Precision)_02". We identified that your firm had invalidated two sets of data pertaining to the precision parameter of the (b) (4) method verification. However, your validation report for the corresponding method (MVR/16/2023) failed to reference these events.

(2) Analytical methods used to ensure the quality of drug products are not validated prior to their transfer from your firm's validation facility. The table below provides examples of analytical procedures that were transferred to the Quality Control Laboratory prior to completing method validation.

In all cases below your firm's Quality Control (QC) unit tested exhibit/submission batches using these non-validated, non-transferred and non-verified analytical test methods.

Name of the Product	Analytical Parameter	Method Validation Protocol Number	Method Validation Report Number	Report Approval Date	Method Transfer Protocol Number	Method Transfer Report Number	Report Approved Date	Product Manufacture Date
(b) (4) (b) (4) ab- lets (b) (4) mg / (b) (4) mg (b) (4) mg & (b) (4) mg (b) (4) mg	Dissolution by HPLC	AMV/P/11-132	AMV/R/11-132	8-Aug-11	AMT/10-098	AMT/10-098	27-Jul-10	26-Jul-10
	Assay & UOD By HPLC	AMV/P/11-133	AMV/R/11-133	8-Aug-11	AMT/10-099	AMT/10-099	27-Jul-10	
	Related Compounds By HPLC	AMV/P/11-134	AMV/R/11-134	8-Aug-11	AMT/10-100	AMT/10-100	29-Jul-10	

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EMPLOYEE(S) SIGNATURE
Massoud Motamed, Investigator
Latorie S. Jones, Investigator

DATE ISSUED
12/16/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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FIRM NAME	STREET ADDRESS
Hetero Labs Limited	TSIIC Pharma SEZ
CITY, STATE, ZIP CODE, COUNTRY Polepally Village, Jadcherla Mandal, Mahaboob Nagar District, Telangana State, 509301, India	TYPE ESTABLISHMENT INSPECTED Oral Solid Dose Drug Product Manufacturer

	BA (b)(4) by HPLC	AMV/P/11-135	AMV/R/11-135	16-Jul-11	AMT/10-097	AMT/10-097	26-Jul-10	
(b) (4) (b) (4) Tablets (b) mg & (b) (4) mg	(b) (4) &UOD by HPLC	AMV/P/12-015	AMV/R/12-015	17-May-12	AMT/P/11-140	AMT/R/11-140	6-Dec-11	21-Dec-11
	Dissolution by HPLC	AMV/P/12-016	AMV/R/12-016	8-May-12	AMT/P/11-141	AMT/R/11-141	10-Dec-11	
	Assay by HPLC	AMV/P/12-017	AMV/R/12-017	15-May-12	AMT/P/11-142	AMT/R/11-142	6-Dec-11	
	Chromatographic purity by HPLC	AMV/P/12-018	AMV/R/12-018	30-May-12	AMT/P/11-143	AMT/R/11-143	10-Dec-11	
	(b) (4) by GC	AMV/P/12-019	AMV/R/12-019	6-Apr-12	AMT/P/11-149	AMT/R/11-149	23-Dec-11	
(b) (4) (b) (4) SP ablets (b) (4) mg & (b) (4) mg	Dissolution by UV	AMV/P/11-150	AMV/R/11-150	20-Sep-11	AMT/P/11-016	AMT/R/11-016	19-Feb-11	17-Feb-11
	BA (b) (4) &UOD By HPLC	AMV/P/11-171	AMV/R/11-171	20-Sep-11	AMT/P/11-015	AMT/R/11-015	19-Feb-11	
	Assay By HPLC	AMV/P/11-172	AMV/R/11-172	20-Sep-11	AMT/P/11-017	AMT/R/11-017	19-Feb-11	
	Related Compounds By HPLC	AMV/P/11-203	AMV/R/11-203	12-Nov-11	AMT/P/11-018	AMT/R/11-018	19-Feb-11	

OBSERVATION 8

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Your firm's Empower 3 based high-performance liquid chromatography (HPLC) system had approximately 421 occurrences of a user abort since roughly September 23, 2016. The majority of these aborts are during data acquisition. However, a sub-set of these user abort events demonstrated a time gap between the last injection (analytical testing) and the user abort event, such that the last injection occurred a significant amount of time prior to the user abort event. Your Deputy Manager of QC stated that they have no documentation pertaining to events not captured between the last injection and the Empower system registering the user abort. There is no record of activity in the Empower system after the last injection recorded and prior to the registry of the user abort. Some examples of the time disparities without investigations are presented in the table below:

Date of Event	Time of User Abort	Last Run Time	Injection Run Length	Time Gap	Product
24-09-2016	(b) (4)		40 Min	51 min	(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Massoud Motamed, Investigator Latorie S. Jones, Investi or	DATE ISSUED 12/16/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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FIRM NAME	STREET ADDRESS
Hetero Labs L m ted	TSIIC Pharma SEZ
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Polepally V llage, Jadcherla Mandal, Mahaboob Nagar District, Telangana State, 509301, India	Oral Solid Dose Drug Product Manufacturer

	(b) (4)			((b) (4))
26-09-2016		20 Min	1hr 10 min	(b) (4) Tablets (b) (4)
29-09-2016		10 Min	44 min	(b) (4) ((b) (4))
29-09-2016		15 Min	36 min	(b) (4) ((b) (4))
29-09-2016		15 Min	36 min	(b) (4) ((b) (4))
04-10-2016		45 Min	1hr 40 min	(b) (4) ((b) (4))
06-10-2016		35 Min	1hr 24min	(b) (4) Tablets ((b) (4))
06-10-2016		40 Min	1hr 14min	(b) (4) ((b) (4))
07-10-2016		15 Min	56 min	(b) (4) Tablets ((b) (4))
24-10-2016		20 Min	2hr 23min	(b) (4) (b) (4))
26-10-2016		30 Min	1hr 3min	(b) (4) Tablets ((b) (4))
08-11-2016		40 Min	2hr 28min	(b) (4) ((b) (4))

(b) (4) = (b) (4) , (b) (4) and (b) (4)
(b) (4) = (b) (4) and (b) (4)
(b) (4) = (b) (4) , (b) (4) and (b) (4)

***DATES OF INSPECTION**
12/07/2016(Wed),12/08/2016(Thu),12/09/2016(Fri),12/12/2016(Mon),12/13/2016(Tue),12/14/2016(Wed),12/15/2016(Thu), 12/16/2016(Fri)

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	Massoud Motamed, Investigator Latorie S. Jones, Investigator	12/16/2016